K073168

APR 28 2008

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap SterilContainer with PrimeLine Lids
November 8, 2007

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Kathy A. Racosky 610-984-9291 (phone) 610-791-6882 (fax)
TRADE NAME:	Aesculap SterilContainer with PrimeLine Lids
COMMON NAME:	Sterilization Container
CLASSIFICATION NAME:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
REGULATION NUMBER:	880.6850
PRODUCT CODE:	KCT

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the *SterilContainer with PrimeLine Lids* is substantially equivalent to:

Aesculap Sterilcontainer System (Flash Indication) (K053389)

Reusable SterilContainer Filter (K041623)

Rigid Container System (K944864)

Aesculap Sterilcontainer System (K792558)

DEVICE DESCRIPTION

The Aesculap SterilContainer with PrimeLine Lid is used in conjunction with Aesculap's Sterilcontainer System (K792558 & K944864). The PrimeLine Container Lid is designed to be compatible for use with pre-vacuum steam and pre-vacuum flash sterilization. The lid is manufactured from Radel R 5000/5008 and utilizes a reusable polytetrafluoroethylene (PTFE) filter.

INDICATIONS FOR USE

The Aesculap Sterilcontainer System is a reusable sterilization container system (consisting of solid and perforated bottoms, a perforated lid w/ filter retention plates, and reusable polytetrafluoroethylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use in pre-vacuum steam and flash sterilization. The SterilContainer System includes accessories such as silicon mats, baskets, trays, and racks.

TECHNOLIGICAL CHARACTERISTICS(compared to predicate(s))

The Aesculap PrimeLine Container Lid is made from Radel R5000/5008 and is similar to Aesculap's Tufflite lid which is manufactured from Jadex. Both are a polyphenylsulfone resin. The PrimeLine Container Lid is compatible for use with pre-vacuum steam and pre-vacuum flash sterilization. Aesculap's Sterilization Container System was cleared for use in pre-vacuum steam and pre-vacuum flash. The PrimeLine Container Lid utilizes an integrated reusable PTFE filter. The reusable PTFE filter is the same as Aesculap's Reusable Sterilcontainer Filter. The PrimeLine Container Lid is offered in a similar range of sizes as the predicates.

PERFORMANCE DATA

The Aesculap Sterilcontainer system was fully validated for the steam and flash sterilization in a prevacuum steam and flash cycle. This validation was conducted in accordance with FDA guidance and available AAMI standards by a qualified testing laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2008

Ms. Kathy A. Racosky
Regulatory Affairs Specialist
Aesculap, Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K073168
Trade/Device Name: Aesculap Sterilcontainer with PrimeLine Lids
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: April 9, 2008
Received: April 10, 2008

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K073168

Device Name: ***Aesculap Sterilcontainer with PrimeLine Lids***

Indications for Use:

The Aesculap Sterilcontainer System is a reusable sterilization container system (consisting of solid and perforated bottoms, a perforated lid w/ filter retention plates, and reusable polytetrafluoroethylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use in pre-vacuum steam and flash sterilization. The SterilContainer System includes accessories such as silicon mats, baskets, trays, and racks.

A combined maximum load validated for all container configurations is 35lbs.			
Sterilization Cycle Parameters	**Lid Size**	**Solid Base to be used with Lid**	**Max No. of Lumens Lumen Configuration**
No stacking recommended for flash cycles **Flash (Non porous)** 270°F Temp, 3 min. Exposure **Flash (mixed)** 270°F Temp, 4 min. Exposure **Prevacuum** Stacking should not exceed 16-18" height 270°FTemp, 4min.Exposure, 15 min. Dry	½ size Lid (11 In x 11 in) Art. No. JP021 – JP027	JK340 (2 in height) JK341 (4 in height) JK342 (5 in height) JK343 (6 in height) JK344 (8 in height) JK346 (9 in height)	2 SS lumens ≥ 3mm I.D. x ≤200mm L
	¾ size Lid (18 in x 11 in) Art. No. JP011 – JP017	JK740 (4 in height) JK741 (5 in height) JK742 (6 in height)	2 SS lumens ≥3 mm I.D. x ≤ 400mm L
	Full size Lid (22 in x 11 in) Art. No. JP001 – JP007	JK440 (4 in height) JK441 (5 in height) JK442 (6 in height) JK444 (8 in height) JK446 (10 in height)	2 SS lumens ≥3 mm I.D. x ≤ 400mm L
Sterilization Cycle	**Lid Size**	**Perforated Base to be used with Lid**	
Stacking should not exceed 16-18" height **Prevacuum** 270°FTemp, 4 min. Exposure, 15 min. Dry	½ size Lid (11 in x 11 in) Art. No. JP021 – JP027	JN340 (2 in height) JN341 (4 in height) JN342 (5 in height) JN343 (6 in height) JN344 (8 in height) JN346 (9 in height)	2 SS lumens ≥3 mm I.D. x ≤200mm L
	¾ size Lid (18 In x 11 In) Art. No. JP011 – JP017	JN740 (4 in height) JN741 (5 in height) JN742 (6 in height)	2 SS lumens ≥ 3mm I.D. x ≤ 400mm L
	Full size Lid (22 in x 11 in) Art. No. JP001 – JP007	JN440 (4 in height) JN441 (5 in height) JN442 (6 in height) JN444 (8 in height) JN446 (10 in height)	2 SS lumens ≥3 mm I.D. x ≤ 400mm L

Prescription Use _____ and/or Over-the-Counter Use X

(per 21 CFR 801 Subpart D) (per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073168